

REMARKS**The Claimed Invention meets 35 U.S.C. § 112, second paragraph requirement**

Claims 4 is rejected under 35 U.S.C. § 112, second paragraph, being indefinite. (Page 2 of Office Action). Applicant respectfully traverses this rejection.

Claim 4 recites that the water weight is based on the total amount of water, chloroformate and hydroxybenzene, not the total amount of chloroformate and hydroxybenzene. Solely to promote the allowance of the case and without acquiescing to the Examiner's rejection, claim 4 has been amended to clearly define the subject matter of the invention. Applicant respectfully requests that this rejection be withdrawn.

The Claimed Invention is Not Obvious

Claims 1-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Steichen *et al.* (U.S. Patent No. 5,705,091, "Steichen *et al.*"). (Pages 2-5 of Office Action). Applicant respectfully traverses this rejection.

"The determination of obviousness is a matter of law based on findings of underlying fact, wherein the factors identified in *Graham v. John Deere Co.*...guide the inquiry...." *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1085, 89 USPQ2d 1370 (Fed. Cir 2008), citing *Graham v. John Deere Co.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); *see also KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007). The factors identified in *Graham* are: (1) "the scope and content of the prior art;" (2) "the differences between the prior art and the claims;" (3) "the level of ordinary skill in the pertinent art;" and (4) "secondary considerations." *Graham*, 383 U.S. at 17-18. "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 127 S.Ct. at 1741.

Thus, the current standard of obviousness takes into account (1) whether there would have been a "reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does;" and (2) whether the combination of elements would have yielded "predictable results" *i.e.*, whether there would have been a reasonable expectation of success. *See e.g.*, *KSR*, 127 S.Ct. at 1741; *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d at 1342, 1360 (Fed. Cir. 2007). Further, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974); *see also* MPEP §2143.03.

Applicant respectfully submits that the pending claims are not obvious Steichen *et al.* for the following reasons.

First, each of claim limitations is not taught or suggested in the prior art, as required for a *prima facie* case of obviousness. The element of using “water” in step (C) of claim 1 is not disclosed nor suggested by the cited art. Further, that element using water in step (C) makes the present invention a very improved method over Steichen *et al.*

In particular, the yield of the example in the present invention is as follows: 33 g of 2-hydroxyethyl decanoate (MW: 216) is 0.15 M and the produced 41.7 g of 2-chlorocarbonyl oxyethyl decanoate (MW: 279) is 0.149 M, and therefore the yield of this step is about 99%. In the last step of the present invention, 73.45 g of 2-chlorocarbonyl oxyethyl decanoate is 0.2637 M and 109.43 g of decanoyloxyethoxycarbonyloxybenzenesulfonate (MW: 437) as the final product is 0.25 M, and therefore the yield of this step is about 94%. Accordingly, the total yield of the method of the present invention is about 93%.

Thus, the present invention provides a very improved method over the cited art, when comparing the high yield of the present invention with about 50% yield of example 1 of Steichen *et al.* (see Column 13, lines 53-57 of Steichen *et al.*). Also, the unexpected results of the claimed invention rebut any such *prima facie* case. *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007); *see also* MPEP §2145.

The disadvantage of the method taught in Steichen *et al.* are described in the present specification. For example, page 2, lines 13~19 of the present specification discloses as follows:

“US patent No. 5,705,091 discloses such an ester bleach activator compound. However, the ester bleach activator compound is made under the conditions: 1) argon gas is used when phosgene is added for reaction, and the reaction temperature should be controlled low at about -78°C, and 2) hydroxybenzene, its derivatives, or its salts are added and reacted in an organic solvent such as methylecyanide (CH₃CN). Thus, the above technique disadvantageously requires very complex manufacturing procedure and shows low yield as much as about 50%.”

In contrast, the high yield of the claimed invention is obtained from using “water” in step (C). The Office has not established the obviousness of the instant claims because it has not established that each of claim limitations is taught or suggested in the prior art, as

required for a *prima facie* case of obviousness. *Abbott* 544 F.3d at 1351, *see also In re Ochiai*, 71 F.3d 1565, 1572. (Fed. Cir. 1995) (PTO must establish “that the invention as claimed in the application is obvious over cited prior art, based on the specific comparison of that prior art with claim limitations.”).

Secondly, the method of Steichen *et al.* employs the complicated steps such as evaporation removal of acetonitrile, addition of ethyl acetate, extraction using sulphuric acid, drying, filtration, concentration, addition of methanol, addition of NaHCO₃, second evaporation and second drying to obtain the final product. However, the present invention can obtain the final product by simple steps such as cooling, filtration, removal of salt and drying, because step (C) uses water as a reaction solvent.

Thirdly, the method using an organic solvent as a reaction solvent in Steichen *et al.* is more conventional than the claimed method using water, because of low reaction rate, yield, and purification.

Fourthly, Steichen *et al.* merely discloses the water solubility difference between the precursors with oxynitrogen leaving group and phenyl sulfonate. In particular, Steichen *et al.* discloses “*For example, the inventive precursors with oxynitrogen leaving group are apparently not as soluble in aqueous media as compared to phenyl sulfonates.*” (see column 9, lines 56-58). This disclosure of Steichen *et al.* is not related to using water as a reaction solvent as recited in the present claims. Steichen *et al.* discloses that it is preferable to use surfactants in a delivery system (see column 9, lines 60-67) because the precursors are less water-soluble.

In view of the foregoing, the claimed invention is not obvious over cited art, based on the specific comparisons of the cited art with claim limitations. *In re Ochiai*, 71 F.3d at 1572.

Furthermore, even assuming, *arguendo*, a *prima facie* case of obviousness were established, there is evidence of unexpected results for the claimed method that rebuts any such *prima facie* case, as discussed above. As well settled, even if a *prima facie* case of obviousness is established, the Examiner is required to consider all rebuttal evidence submitted by an applicant. *See In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007); *see also* MPEP §2145. This requirement remains unchanged following the decision in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), as the Federal Circuit has made clear in *In re Sullivan*, 498 F.3d at 1351. As the Court explained, “[w]hen a patent applicant puts forth rebuttal evidence, the Board must consider that evidence.” *Id.* at 1351. Such rebuttal evidence includes “evidence of unexpected results.” *Id.*, citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d

1348, 1369 (Fed. Cir. 2007).

These unexpected results are sufficient to rebut a *prima facie* case of obviousness. *In re May*, at 1094; *In re Chupp*, at 646; and *Ortho-Mcneil Pharmaceutical v. Mylan Laboratories*, at 755. Therefore, the claimed invention is not obvious and Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be withdrawn.


CONCLUSION

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner reconsider this application with a view towards allowance.

No fees are believed due in connection with this Amendment. However, the Commissioner is authorized to charge any required fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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